Statement for the Record

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INTRODUCTION

Good afternoon, Chairman Shays, Congressman Kucinich and distinguished members of the Subcommittee. I am pleased to appear before you today to discuss the role that the Department of Homeland Security's (DHS) threat and risk assessments play in informing and prioritizing research and development of new medical countermeasures.

Before focusing on the Department's specific activities in the area of threat and risk assessments, I would like to put these activities in the broader context of the overall responsibilities and activities of the DHS Biological Countermeasures Portfolio (Bio Portfolio) which I direct. The mission of this Portfolio is to provide the understanding, technologies, and systems needed to anticipate, deter, protect against, detect, mitigate, and recover from possible biological attacks on this nation's population, agriculture or infrastructure.

In addressing this mission, DHS has a leadership role in several key areas and partners with lead agencies in others. Those areas in which the Science and Technology (S&T) Directorate provides significant leadership are:

- Providing an overall end-to-end understanding of an integrated biodefense strategy, so as to guide the Secretary and the rest of the Department in its responsibility to coordinate the nation's efforts to deter, detect, and respond to acts of biological terrorism.

- Providing scientific support to better understand both current and future biological threats and their potential impacts so as to guide the research and development of biodefense countermeasures such as vaccines, drugs, detection systems and decontamination technologies.

- Developing early warning, detection and characterization systems to permit timely response to mitigate the consequence of a biological attack.

- Conducting technical forensics to analyze and interpret materials recovered from an attack to support attribution.

- Operation of the Plum Island Animal Disease Center to support both research and development (R&D) and operational response to foreign animal diseases such as foot and mouth disease.

DHS also supports our partnering departments and agencies with their leads in other key areas of an integrated biodefense: the Department of Health and Human Services (HHS)

on medical countermeasures and mass casualty response; the Department of Defense (DoD) on broad range of homeland security/homeland defense issues; the U.S. Department of Agriculture (USDA) on agriculture biosecurity; USDA and HHS on food security; the Environmental Protection Agency (EPA) on decontamination and on water security; the Department of Justice on bio-terrorism investigations; and the Intelligence Community on threat warnings.

THREAT AND RISK ASSESSMENTS

As noted above, providing threat and risk assessments of both current and future threats and the scientific understanding to improve and refine these assessments is a major responsibility for DHS. These responsibilities are further defined in the BioShield Act of 2004, which charges the Secretary of DHS with the responsibility for determining which threats constitute a Material Threat to the national security or public health of the Nation and in the President's *Biodefense for the 21st Century,* which charges DHS with the lead in "conducting routine capabilities assessments to guide prioritization of our ongoing investments in biodefense-related research, development, planning and preparedness".

Today, I would like to focus on four major activities that we have undertaken to fulfill these responsibilities:

1. Material Threat Assessments and Determinations in support of Project BioShield;
2. Risk Assessments to guide prioritization of the Nation's ongoing biodefense-related activities;
3. A Strategy for Addressing Emerging Threats (in partnership with the Department of Health and Human Services (DHHS) and others);
4. Scientific research to better inform these threat and risk assessments.

Material Threat Assessments and Determinations for Project BioShield

Working with the DHS Directorate for Information Analysis and Infrastructure Protection (IAIP), DHS S&T has been conducting assessments and determinations of biological, chemical, radiological and nuclear agents of greatest concern so as to guide near-term BioShield requirements and acquisitions. In this process, IAIP, in concert with other members of the intelligence community, provides information on the capabilities, plans and intentions of terrorists and other non-state actors. However, since lack of intelligence on a threat does not mean lack of a threat, S&T, in concert with appropriate members of the technical community, also assesses the technical feasibility of a terrorist being able to obtain, produce and disseminate the agent in question. This information is used to establish a plausible high consequence scenario that provides an indication of the number of exposed individuals, the geographical extent of the exposure, and other collateral effects. If these consequences are of such a magnitude to be of significant concern to our national security or public health, the Secretary of DHS then issues a formal Material Threat Determination to the Secretary of HHS, which initiates the BioShield process.

To date, the Secretary of DHS has issued Material Threat Determinations for four "agents": anthrax, smallpox, botulinum toxin, and radiological/nuclear devices. Additional threat assessments are underway for the remainder of the agents (plague, tularemia, viral hemorrhagic fevers) identified by the Centers for Disease Control and Prevention as Category A agents and for chemical nerve agents. These assessments will be completed this fiscal year.

Once a Material Threat Determination (MTD) has been issued, the HHS then assesses the potential public health consequences of the identified agent and determines the need for countermeasures. After notifying Congress of its determination, HHS evaluates the availability of current countermeasures and the possibility of development of new countermeasures. They are assisted in this by the interagency Weapons of Mass Destruction Medical Countermeasures (WMD-MC) subcommittee of the Office of Science and Technology Policy's National Science and Technology Council (NSTC). The WMD-MC further explores the medical consequences associated with the particular threat and the availability of appropriate countermeasures so as to develop a recommendation for the acquisition of a specific countermeasure. These recommendations then form the basis of the U.S. Government requirements. After approval of these requirements by the Office of Management and Budget, the HHS issues a Request for Proposals and implements and manages the subsequent acquisition process through delivery of the countermeasures to the Strategic National Stockpile.

Risk Assessments to Guide Prioritization of the Nation's Biodefense Activities

The preceding discussion dealt with threat assessments to guide BioShield acquisition processes. DHS has an even broader responsibility in the President's National Biodefense Strategy and that is to conduct formal, periodic risk assessments, in coordination with other Departments and agencies, to guide the prioritization of the nation's ongoing biodefense activities – not just medical, but also including such areas as surveillance and detection, decontamination and restoration, and forensics. These risk assessments provide a systematic look at the technical feasibility of a broad range of biological threats, the vulnerability of different portions of our society to those threats, and the resulting consequences of any such attacks.

The first such formal risk assessment is due in the winter of 2006, with subsequent assessments due every two years. The scope, process and timescale for this first assessment have been presented to and agreed to by the interagency Biodefense Policy Coordinating Committee co-chaired by the Homeland Security Council and the National Security Council. This assessment is addressing:

- All six category A agents from the Centers for Disease Control and Prevention (CDC) threat list;
- All 12 category B agents;
- Five representative category C agents; and
- A number of candidate drug-resistant and emerging agents.

Key outputs will include:

- A list of bio-threats prioritized by risk;
- A prioritized list of critical knowledge gaps that if closed should reduce risk assessment uncertainty and guide bio-defense research and development; and
- A list of biodefense vulnerabilities that could be reduced by countermeasure development and acquisition.

This risk assessment is being conducted in partnership with the Intelligence Community, the HHS, the Department of Defense, the U.S. Department of Agriculture, the Environmental Protection Agency and others. Two advisory boards, one a Government Stakeholders Advisory Board and the other an Independent Risk Assessment Expert Review Board (academia, industry and government) have been established to provide input and advice.

This and subsequent risk assessments will play a critical role in informing future biodefense programs across all agencies, including BioShield acquisitions and the longer-term medical R&D leading up to such acquisitions.

A Strategy for Addressing Emerging Threats

Much of the biodefense efforts to date have focused on protecting against attacks with bioterrorism agents that can be (or used to be) found in nature. However, rapid advances in biotechnology demand that we also consider the possibility and impact of emerging or engineered agents. e.g. modifications to organisms that increase their resistance to medical countermeasure or make them more difficult to detect. The President's *Biodefense for the 21st Century* assigns the HHS the lead in anticipating such future threats. We, DHS S&T, are partnering with HHS and others in formulating and implementing a strategy for anticipating and responding to such threats.

Based on intelligence information, available literature and expert judgment, we have developed an informed estimate of the types of emerging threats that might be within the ability of a terrorist organization to develop over the near (1-3 years), mid (4-10 years), and longer-terms (10 yrs). We have also examined the impact of these threats on the four pillars of the National Biodefense Policy: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.

In this analysis, four elements stand out as essential to an effective defense against emerging threats:

- Threat, vulnerability and risk assessments to prioritize these threats in terms of the difficulty of their development and deployment, as well as their potential consequences;
- Surveillance and detection capabilities to rapidly detect and characterize engineered agents in environmental and clinical samples so as to provide timely guidance in the selection of the appropriate medical countermeasure;

- An expanded range of safe and effective medical countermeasures and an infrastructure to support rapid research, development, test and evaluation (RDT&E) of new medical countermeasures; and
- integrated concepts of operation (CONOPS) for the identification and response to emerging threats. In addition to conducting these assessments, DHS will continue to collaborate with HHS as it leads efforts to anticipate agents and to facilitate the availability of medical countermeasures.

Scientific research to better inform these threat and risk assessments

The threat and risk assessments described above are performed with the best available information. However, there are large uncertainties, sometimes factors of ten to a hundred, in some of the key parameters and hence in the associated risks. One of the major functions of the threat and risk assessments is to identify these critical knowledge gaps, which can differ for different threat scenarios – in one case it can be the minimum amount of agent needed to infect a person; in another case it can be the time that such an agent remains viable (capable of causing an infection) in the air, food or water; and in a third it can be the effect of food processing or water treatment on the agent's viability. Conducting the laboratory experiments to close the critical knowledge gaps is a primary function of DHS's National Biodefense Analysis and Countermeasures Center (NBACC).

Congress has appropriated a total of $128M for design and construction of NBACC with the necessary biocontainment laboratory space and support infrastructure to conduct these and other experiments. NBACC will be built on the National Interagency Biodefense Campus (NIBC) at Ft. Detrick MD, where its close physical proximity to the DoD's United States Army Medical Research Institute for Infectious Diseases (USAMRIID), the NIH's Integrated Research Facility and the USDA's Foreign Disease-Weed Science Research Unit. NBACC is also collaborating with the Centers for Disease Control and Prevention to further address the critical knowledge gaps. The Record of Decision for NBACC's Final Environmental Impact Statement was signed in January 2005. Design of the facility began in March 2005, with construction scheduled to begin in FY 2006 and be complete by the fourth quarter of FY 2008.

Currently, interim capabilities for both NBACC's biological threat awareness and bioforensic analysis functions have been established with other government and private laboratories to allow vital work in these areas to occur during the NBACC facility's construction.

CONCLUSION

In summary, the DHS Science and Technology Directorate's programs in threat and risk assessment play a critical role in the interagency process to develop medical countermeasures against weapons of mass destruction. These threat and risk assessments are conducted in active collaboration with other Federal departments and agencies and with the appropriate technical experts in the government, academia and the private sector

as we collectively seek to reduce the threat of a biological attack against this nation's population, its agriculture and its food supply.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Congressman Kucinich , and Members of the Subcommittee, I thank you for the opportunity to appear before you and I will be happy to answer any questions that you may have.